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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,227	07/02/2003	Jeffrey Grossman	31132.164	1226
46333	7590	02/03/2006	EXAMINER	
HAYNES AND BOONE, LLP 901 MAIN ST SUITE 3100 DALLAS, TX 75202			POUS, NATALIE R	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/604,227	GROSSMAN, JEFFREY	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/22/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed December 19, 2005 have been fully considered but they are not persuasive.

Regarding rejections under 35 U.S.C. 112:

Applicant argues that paragraph [0019] discloses an embodiment wherein a reflecting element is not required. Examiner disagrees with this argument for the following reason: Paragraph [0019] discloses an embodiment wherein the teacher may use the trajectory of the light as a reference point within the room to help teach the student the correct trajectory. As such, the surface within the room that the trajectory of the light shines on is reflecting that light so the teacher can see the trajectory of the needle. Without a wall or a ceiling for the light to reflect on there would be no visual cue from the light as to the trajectory of the needle, rendering the device non-enabling. As such, examiner sustains prior rejections under first and second paragraphs of 35 U.S.C. 112.

Regarding rejections under 35 U.S.C. 102:

Applicant argues that Burgin and Karram do not disclose an energy source that indicates trajectory corrections required for the insertion device. Examiner asserts that both Burgin and Karram teach insertion devices that illuminate the area at which the devices will make contact. Once the user illuminates an area, it is clear whether the area illuminated is the correct insertion area or not. If the area illuminated by the device is not the correct insertion site the user may move the device to another location,

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therefore using the devices to indicate a required trajectory correction. In light of this explanation, examiner sustains that Burgin and Karram anticipate claim 1, teaching every element of the claim under 35 U.S.C. 102.

Regarding remarks relating to claims 3, 4, 6-9, 11 and 12:

As previously disclosed, both Burgin and Karram do in fact teach all elements of claim 1, therefore examiner sustains prior rejections of claims 3, 4, 6-9, 11 and 12 under 35 U.S.C. 102.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Regarding remarks relating to claim 5:

As previously disclosed, Karram does in fact teach all elements of claim 1, therefore examiner sustains prior rejections of claim 5 under 35 U.S.C. 102.

Regarding remarks relating to claim 13:

Applicant argues that Burgin and Karram do not disclose a surface for indicating any alignment correction required for the insertion device. As applicant points out, Burgin provides for "an instrument which the field upon which the instrument is to be used can be illuminated by the instrument." Examiner asserts that a field upon which an instrument is to be used is inherently a surface of some kind. That, in conjunction with examiners previous explanation with regards to claim 1 as to required trajectory leads

the examiner to sustain the prior rejection of claim 13 under 35 U.S.C. 102(b) with respect to Burgin. Similarly, Karram discloses a device for illuminating tissue (114) at the point of insertion. Examiner asserts that claim 13 does not require that the reflecting element and the surface for indicating a location of the reflected energy path be different, and as such, when the surface is illuminating the tissue, it is simultaneously reflecting the light to give the user a visual cue as to the trajectory of the light, and indicating the surface as to which the device will make an insertion. Further, if the reflected light on the tissue does not illuminate desired insertion site, the user may move the device so the correct area is illuminated. Based on this explanation, examiner sustains the prior rejection of claim 13 under 35 U.S.C. 102(a) with respect to Karram.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant argues Karram does not teach a surface, however examiner asserts as disclosed in the prior office action, Karram teaches all elements of claim 13, including surface (114). Applicant does not distinctly point out as to how the claimed surface is different than the surface disclosed by Karram.

Regarding remarks relating to claims 14-16:

As previously disclosed, Karram does in fact teach all elements of claim 13, therefore examiner sustains prior rejections of claims 14-16 under 35 U.S.C. 102.

Regarding remarks relating to claim 18:

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As previously described in regards to claim 1, Burgin does disclose reflecting the energy path so that a proximity of the reflected energy path to the energy source indicates any alignment correction required for the insertion device. Therefore, examiner sustains the prior rejection of claim 18 under 35 U.S.C. 102(b) with respect to Burgin.

Similarly, Paltieli discloses an insertion device as a whole including an energy source and an insertion member. The energy source is applied to a surface and if the surface is the desired insertion site, the insertion member will insert at that point. However, if the energy source is not applied to the desired insertion site as viewed on the controller, the user may move the energy source to the correct insertion site and employ the insertion member at that site. Therefore, the 102(b) rejection of claim 18 is in fact supported by Paltieli, and examiner sustains the prior rejection of claim 18 under 35 U.S.C. 102(b) with respect to Paltieli.

Regarding remarks relating to claims 19-21:

As described above, both Burgin and Paltieli teach all elements of preceding dependent claim 18, therefore the 102(b) rejection of claims 19-21 is supported by Burgin and Paltieli, and is therefore sustained.

Rejections under 35 U.S.C. 103

Regarding remarks relating to claim 10:

Applicant argues that examiner has not factually supported a prima facie case of obviousness with the combination of Karram and Pirtle for the following reasons: (1) even when combined, the references do not teach the claimed subject matter, and (2) the combination of references is improper.

(1) as described previously, Karram does in fact disclose all aspects of claim 1 including indicating trajectory corrections required for the insertion device, thus the explicit terms of 103 are met, and examiner has factually supported a prima facie case of obviousness.

(2) In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, applicant argues no suggestion of combination due to the fact that neither device teaches an energy source that indicates a trajectory correction requirement. Examiner asserts that Karram teaches a device that may be placed on any medical device and indicates trajectory

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correction requirement as described previously. Therefore, it would have been obvious to modify Pirtle with the energy source of Karram since Karram states the device may be used on any medical device to illuminate the desired incision site, thus the explicit terms of 103 are met, and examiner has factually supported a prima facie case of obviousness.

For the reasons described above, examiner sustains prior rejection of claim 10 under 35 U.S.C. 103(a)

Regarding remarks relating to claims 13 and 17:

Applicant argues that examiner has not factually supported a prima facie case of obviousness with the combination of Kitaevich and Yanof for the following reasons: (1) even when combined, the references do not teach the claimed subject matter, and (2) the combination of references is improper.

(1) applicant argues neither kitaevich or Yanof teach an energy source located on an insertion device. Examiner asserts that a device as a whole may be made up of a sum of parts working together. As such in the device of Kitaevich, when relating to insertion device (30) as a whole, energy source (106) is located on the insertion device, thus the explicit terms of 103 are met, and examiner has factually supported a prima facie case of obviousness.

(2) In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

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references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, as described above, Kitaevich does in fact teach an energy source located on an insertion device and as such, with regards to applicants remarks, explicit terms of 103 are met, and examiner has factually supported a prima facie case of obviousness.

For the reasons described above, examiner sustains prior rejection of claim 13 under 35 U.S.C. 103(a). Further, since claim 17 depends from claim 13, the examiner's burden of factually supporting a prima facie case of obviousness has been met with respect to claim 17, and examiner sustains prior rejection of claim 17 under 35 U.S.C. 103(a).

Rejections under double patenting:

Examiner acknowledges submission of terminal disclaimer.

Terminal Disclaimer

The terminal disclaimer filed on December 19, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6605095 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A reflecting element, critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Paragraph 5 of the disclosure teaches "The present alignment system comprises an insertion device, an energy source and a reflecting element." It is understood that the energy source reflects off the reflecting element onto the insertion device therefore creating an alignment trajectory. Claim 1 does not disclose the reflecting element, therefore rendering the device incapable of performing its disclosed function.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 describes an insertion trajectory device comprising an energy source and an insertion device, omitting the reflecting element described in the disclosure, therefore claiming that the trajectory system is useful without the reflecting element. See *In re Gentry*, claims must not be broader than the supporting disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the reflecting element. It is required by the disclosure that the insertion device trajectory system include a reflecting element for the light source to reflect off of in order to create a trajectory path. Without this element, it is impossible for the device to function as disclosed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16, 18 and 19, are rejected under 35 U.S.C. 102(b) as being anticipated by Burgin (US 4657012).

Regarding claims 1, 4 and 8, Burgin discloses an energy source (442) for producing an energy path in a direction away from a medical insertion device indicating any trajectory correction required, and a permanent mechanism (446, 436) by which the

energy source being a light source (442) is attached to the insertion device (Column 3, proximate lines 30-40)

Regarding claim 3, Burgin discloses a surface (222) for indicating the trajectory of the energy path.

Regarding claims 6 and 12, Burgin further discloses an embodiment (Figure 1) wherein the energy path comprises a directed light (132) and the attachment mechanism (32) is adapted to direct the light towards a reflecting element (52) being a reflective radiolucent material. Burgin discloses the handle portion constructed at least partially from a light-transmissive and optical waveguiding material (Column 1, proximate lines 25-30), and a portion of the handle may be polished or plated with a composition, which exhibits a mirror surface (Column 2, proximate lines 40-45).

Regarding claim 7, Burgin discloses the light source positioned so the light directed towards the reflecting element (152) is visibly identifiable on the surface (122).

Regarding claim 9, Burgin further discloses an insertion device comprising a workpiece (22) coaxial with energy source (40) producing an energy path and a visual indicator of the energy path trajectory (Column 1, proximate lines 25-32).

Regarding claim 11, Burgin discloses a visual indicator for indicating a trajectory of the energy path (Column 2, proximate lines 45-50). Burgin further discloses the invention wherein the energy path emanates from the energy source (240) in a direction away from the insertion device (261).

Regarding claims 13, 14 and 15, Burgin discloses an energy source (442) located on an insertion device (436, 446) for producing an energy path in a direction

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away from a medical insertion device indicating any alignment correction required, and wherein the energy path is directed towards a reflecting element (52) being a reflective radiolucent material. Burgin discloses the handle portion constructed at least partially from a light-transmissive and optical waveguiding material (Column 1, proximate lines 25-30), and a portion of the handle may be polished or plated with a composition, which exhibits a mirror surface (Column 2, proximate lines 40-45). Burgin discloses a surface (222) for indicating the trajectory of the energy path.

Regarding claim 16, Burgin discloses the energy source being a light source (442).

Regarding claims 18 and 19, Burgin discloses a method of aligning a medical insertion device comprising generating an energy path from an energy source located on an insertion device (Column 1, proximate lines 60-65), so that a proximity of the reflected energy path to the energy source indicates any alignment correction required for the insertion device in a direction away from the insertion device (Column 2, proximate lines 45-50).

Claims 1, and 5 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Karram (US 6428180).

Karram discloses an energy source (102) for producing an energy path in a direction away from a medical insertion device and a mechanism (112) by which the

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energy source can be attached to the insertion device. Karram further discloses the energy source comprising a LED (Column 4, proximate lines 10-15).

Claims 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Paltieli (5647373).

Regarding claim 18, Paltieli discloses a method of aligning a medical insertion device comprising generating an energy path from an energy source (4) located on an insertion device (Figure 1); and reflecting the energy path so that a proximity of the reflected energy path to the energy source indicates any alignment correction required for the insertion device.

Regarding Claim 19, Paltieli discloses the method wherein the energy path emanates away from the insertion device (Figure 3).

Regarding Claim 20, Paltieli teaches operating the insertion device through a driver (5).

Regarding Claim 21, Paltieli teaches the insertion device comprising a needle (6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karram in view of Pirtle (US 3628523). Karram discloses all aspects of claims 1 and 9 as disclosed above but does not disclose that the workpiece be a needle. Karram does however disclose that the surgical illumination device is detachably mountable in a variety of ways on any suitable surgical instrument (Column 2, proximate lines 45-55). Pirtle discloses a percutaneous needle (Column 1, proximate lines 55-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Karram with a percutaneous needle as taught by Pirtle in order to fulfill the devices capability of use on any surgical instrument.

Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitaevich (US 5598269) in view of Yanof (US 5957933). Kitaevich discloses a medical alignment system comprising an energy source (106) wherein the energy source produces an energy path (104) wherein the energy path is reflected by a reflecting element (103) and a surface (106) for indicating a location of the reflected energy path (108) so that the proximity of the reflected energy path to the energy source

indicates any alignment correction required for the insertion device (Column 3 lines 60-67), wherein the insertion device comprises a needle (100). Kitaevich does not disclose the medical insertion device wherein the energy source is located on the insertion device. Yanof teaches a medical insertion device (30) comprising needle guide (112) thereby attaching the insertion device to energy source (108). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kitaevich as with a needle guide attached to energy source to attach the insertion device to the energy source as taught by Yanof in order to increase stability of the needle and decrease the possibility of human error when the surgeon is utilizing the insertion device.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP
1/18/06


(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER